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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/585,645	06/01/2000	Huda Y. Zoghbi	P01899US2	4965

26271 7590 05/20/2003  
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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/20/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/585,645

Applicant(s)

ZOGHBI ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-48, 112-119, 121, 123 and 124 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 40-48, 112-119, 121, 123 and 124 is/are rejected.

- 7) ☒ Claim(s) 40-48, 112-119, 121, 123 and 124 is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18, 21, 24.                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 40-48, 112-119, 121, 123 and 124 are pending in the application.

This Office Action is in response to the Amendment filed on 3/11/03.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/03 has been entered.

#### ***Response to Amendment***

The rejection of claims 40-48, 112-119, 121 and 123 under 35 U.S.C.112 2<sup>nd</sup> paragraph has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 40-48, 112-119, 121 and 123 under 35 U.S.C.112 1<sup>st</sup> paragraph (written description) has been withdrawn in light of Applicants' amendment of the claims.

Claims 40-48, 112-119, 121, 123 and 124 are objected to for reasons discussed below.

Claims 40-48, 112-119, 121, 123 and newly added claim 124 are rejected under 35 U.S.C.112 1<sup>st</sup> paragraph (enablement) for reasons set forth of the record mailed on 11/19/02 and further discussed below.

Art Unit: 1636

***Claim Objections***

Claims 40-48, 112-119, 121, 123 and 124 are objected to for containing non-elected subject matter. The claims encompass SEQ ID NO:70, however, Applicant elected SEQ ID NO:58 for examination in paper no.15. Amending the claims such that they are only directed to elected inventions is required.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-48, 112-119, 121, 123 and 124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the enablement rejection, Applicants assert that the instant specification and the state of art support the enablement of the claimed invention. Applicants cited Staecker et al., Jero et al., Sover et la., and Lalwani et al. which demonstrate successful gene delivery to inner ear other than direct injection. Therefore, Applicants conclude that the claimed method and composition is enabled for direct delivery of nucleic acid to inner ear.

Art Unit: 1636

Applicants' argument have been fully considered and deemed partially persuasive. The Examiner agrees that the route of delivery may be extended to direct delivering a nucleic acid to inner ear instead of direct injection, however, the instant specification and the cited references do not support delivering the nucleic acid to inner ear using a cell or a bacterial toxin receptor binding domain. Although the cited references teach a number of methods of delivering nucleic acid to inner ear including surgical or non-surgical methods and applying viral or non viral vector coupled with delivery vehicle such as liposome, none of the reference teaches a method of delivering the nucleic acid to inner ear through a cell, a carbohydrate, a peptide or a bacterial toxin receptor binding domain. The unpredictability of the successful gene therapy relating to the technical difficulties of gene delivery was discussed Office Action mailed on 6/3/02 and 11/19/02. Therefore, the enablement of the claimed method and composition must be fully supported by the specification. The instant specification does not provide support for successful gene delivery to inner ear by using a cell, a carbohydrate, a peptide or a bacterial toxin receptor-binding domain. Therefore, whether such delivery method would achieve sufficient gene expression in inner ear and inducing hair cell generation is unpredictable. Without teaching from the specification and the art, one skilled in the art would have to engage in undue experimentation to practice the claimed method or use the composition in commensurate with the scope of the claims.

The specification discloses that the method of generating hair cells in the inner ear is for treating animals with hearing loss and restores vestibular function (see Example 1). The specification only discloses that expressing Math1 in Drosophila lacking ato expression restores the growth of external sensory organ. The Gao reference cited by Applicants teaches that Math1

Art Unit: 1636

induces hair cell differentiation in *ex vivo* cochlea culture. Although damage to inner ear hair cells can cause hearing loss, hearing loss can also result from damage to other parts of auditory organ such as basilar membrane. The specification does not teach whether inner ear hair cell generation can treat hearing loss or restore vestibular function. As such, the nexus between hearing restoration and the hair cell generation is missing. Therefore, whether the claimed method can be used to restore hearing loss result from damages other than hair cell is unpredictable. Similarly, whether inducing inner ear hair growth can restore vestibular function is unpredictable. As such, one skilled in the art would have to engage in undue experimentation to use the method as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Application/Control Number: 09/585,645

Page 6

Art Unit: 1636

Celine Qian, Ph.D.

May 19, 2003



**JAMES KETTER  
PRIMARY EXAMINER**